REMARKS

Reconsideration of the application is respectfully requested in view of the following remarks. Claims 1-23 were pending in the present application. Claims 1-23 are subject to a restriction requirement. Claims 1-23 are currently pending.

RESTRICTION REQUIREMENT UNDER 35 U.S.C. 121

The Examiner indicated that the inventions listed as Groups do not relate to a single inventive concept under 35 USC 121 or PCT Rule 13.1 (unity of invention). The Examiner has required restriction to one of the following inventions under 35 USC 121 and 35 USC 372:

Group I. Claims 1-16 (in part), drawn to nonheterocyclic derivatives of formula I including its salts, and its pharmaceutical compositions; a single disclosed specie is requested for search purposes.

Group II. Claims 1-16 (in part), drawn to benzofuran derivatives of formula I including its salts, and pharmaceutical compositions; a single disclosed specie is requested for search purposes.

Group III. Claims 1-16 (in part), drawn to benzopyran derivatives of formula I including its salts, and pharmaceutical compositions; a single disclosed specie is requested for search purposes.

Group IV. Claims 1-16 (in part), drawn to benzodioxan derivatives of formula I including its salts, and pharmaceutical compositions; a single disclosed specie is requested for search purposes.

Group V. Claims 1-16 (in part), drawn to tetrahydrocarbazole derivatives of formula I including its salts, and pharmaceutical compositions; a single disclosed specie is requested for search purposes.

Group VI. Claims 1-16 (in part), drawn to compounds of formula I not set forth above including its salts, and pharmaceutical compositions; a single disclosed specie is requested for search purposes.

Group VII. Claims 17-22 (in part), drawn to methods of mediating disease by cannabinoid-1 receptor using compounds of formula I wherein A is carbocyclic.

Group VIII. Claims 17-22 (in part), drawn to methods of mediating disease by cannabinoid-1 receptor using compounds of formula I wherein A is furanyl or thiophenyl.

Group IX. Claims 17-22 (in part), drawn to methods of mediating disease by cannabinoid-1 receptor using compounds of formula I wherein A is pyridinyl.

Group X. Claims 17-22 (in part), drawn to methods of mediating disease by cannabinoid-1 receptor using compounds of formula I wherein A is thiazoyl.

Group XI. Claims 17-22 (in part), drawn to methods of mediating disease by cannabinoid-1 receptor using compounds of formula I wherein A is 5 member one N heterocyclic containing.

Group XII. Claims 17-22 (in part), drawn to methods of mediating disease by cannabinoid-1 receptor using compounds of formula I wherein A is heterocyclic containing.

Group XIII. Claims 17-22 (in part), drawn to methods of treating or psychosis, memory deficit, cognitive disorders, migraine, neuropathy, neuron-inflammatory disorders, cerebral vascular accidents, head trauma, anxiety disorders, stress, epilepsy, Parkinson's disease, schizophrenia, substance abuse disorders, constipation, chronic intestinal pseudo-obstruction, cirrhosis of the liver, asthma, obesity and other eating disorders associated with excessive food intake using the compounds of formula I wherein A is as set forth in each of Groups I-VI above.

Group XIV. Claims 19-22 in part, drawn to methods of treating eating disorders associated with excessive food intake using compounds of formula I wherein A is furanyl or thiophenyl.

Group XV. Claim 22 in part, drawn to methods of preventing obesity using compounds of formula I wherein A is pyridinyl.

Group XVI. Claims 17-22, 23 in part, 24 and 30, drawn to methods of treating or preventing diabetes using compounds of formula I wherein Ar is thiazoyl.

Group XVII. Claims 17-22, 23 in part, 24-25, drawn to methods of treating or preventing diabetes using compounds of formula I wherein Ar is 5 member one N heterocyclic containing.

Group XVIII. Claims 17-22, 23 in part, and 24, drawn to methods of treating or preventing diabetes using compounds of formula I wherein Ar is heterocyclic containing.

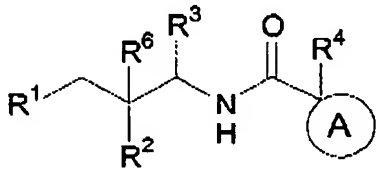
Applicants hereby provisionally elect Group IV Claims 1-16 (in part), drawn to benzodioxan derivatives of formula I including its salts, and pharmaceutical compositions, with traverse.

Under PCT Rule 13.1, the International Application shall relate to one invention only or to a group of inventions so linked as to form a "single general inventive concept." Under PCT Rule 13.2 where a group of Inventions is claimed in the same International Application, the requirement of the

unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a "technical relationship" among those inventions involving one or more of the same or corresponding "special technical features." The term "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description.

Applicants respectfully submit that the instant application complies with the requirement for unity of invention. Under Markush practice governed by Rule 13, the requirement of a technical interrelationship with the same or corresponding special technical features, as defined under Rule 13.2, is considered to be met when the alternatives are of a similar nature. According to Rule 13.2(i), when the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled: (A) all alternatives have a common property or activity, and (B)(1) a common structure is present, i.e. a significant structural element is shared by all of the alternatives. Applicants submit that the compounds of structural formula (I), in which the R1, R2, R3, R4, R6 and A substituents represent alternatives, have the common property of being cannabinoid -1 receptor antagonists/inverse agonists that are useful to treat or prevent disorders, diseases or conditions responsive to the antagonism or inverse agonism of the cannabinoid -1 receptor, such as obesity, and diabetes.

Applicants further submit that the significant structural element shared by all of the alternative compounds in claims 1-23 of the present invention is the core structure, or common chemical structure, of formula (I):



(I)

wherein A is a 3- to 8-membered monocyclic saturated ring optionally containing one to two heteroatoms chosen from oxygen, nitrogen, and sulfur, and to which an aryl or heteroaryl ring is fused, wherein said bicyclic ring is optionally fused to another aryl or heteroaryl ring to form a tricyclic ring. The commonly shared core structure of formula (I) constitutes a structurally distinctive portion of the molecule.

Applicants further submit that the "special technical relationship" that links the various putative inventions into a "single inventive concept" is the ability of the instant compounds of formula (I) to antagonize or inversely agonize the cannabinoid -1 receptor in a human or an animal. The compounds of structural formula (I) provide the common "special technical feature" among these groups. In this regard, the Examiner's attention is drawn to Annex B, Part 2 of PCT Gazette – Section IV, No. 03/2001, entitled "Examples Concerning Unity of Invention", in particular, Example 1 on page 52 and Examples 15 and 16 on page 55.

Applicants respectfully submit that the methods of Group VIII are related to the compounds structural formula (I) in Groups I-VI as product and process of use. The method for determining unity of invention under Rule 13 permits the inclusion of a claim for the use of the product. The present invention is directed to compounds of formula (I), which are cannabinoid -1 receptor antagonists/inverse agonists useful for the treatment or prevention of disorders, diseases or conditions responsive to the antagonism or inverse agonism of the cannabinoid-1 receptor. The specification of the present application notes that it is known in the art that antagonism or inverse agonism of the cannabinoid-1 receptor would be beneficial for the alleged utilities, including the treatment and prevention of obesity and diabetes. Applicants respectfully submit that the compound of structural formula (I), in Groups I-VI and in the method claims 17-22 of Group VIII, is in fact the common special technical feature required by the Examiner. It is the compound of structural formula (I) that is the contribution that this invention, as a whole, makes over the prior art. The primary active ingredient employed in the method claims 17-22 (Group VIII) is a compound of structural formula (I). Furthermore, the technical relationship linking Groups I-VI and Group VIII is the ability of the compounds of formula (I) to antagonize or inversely agonize the cannabinoid -1 receptor in a human or an animal.

Applicants submit that Claim 23 relates to compositions of the compounds of formula I in Groups I-VI and should be included in Groups I-VI. There is a common technical feature between Claim 23 and Groups I-VI. The primary active ingredient employed in the composition claim 23 is a compound of structural formula (I). The special technical feature in composition Claim 23 is a compound of structural formula (I). It is the compound of structural formula (I) that is the contribution that this invention, as a whole, makes over the prior art. The composition claim 23 merely employs the active ingredient, which corresponds to the compound of formula (I), with a pharmaceutically acceptable carrier.

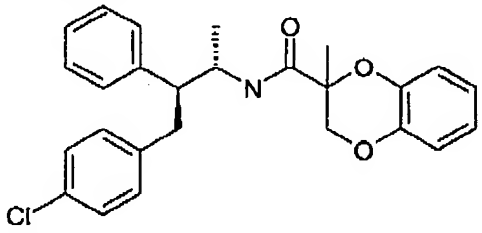
Applicants submit that Groups XVI, XVII and XVII of this restriction requirement include Claim 23, but also include Claims 24-30, which are no longer pending in the current application. Additionally, Applicants submit that Groups XVI, XVII and XVIII of this restriction requirement do not appear to apply to the present application since Ar is not a term used in the definition of the compounds of formula I. Applicants respectfully request that the Examiner include Claim 23 in Groups I-VI instead of Groups XVI-XVIII, which do not appear to apply to the present patent application.

Applicants respectfully request that Group IV, include the compounds of Groups I, II, III and V, wherein A is a 3- to 8-membered monocyclic saturated ring optionally containing one to two heteroatoms chosen from oxygen, nitrogen, and sulfur, and to which an aryl or heteroaryl ring is fused, wherein said bicyclic ring is optionally fused to another aryl or heteroaryl ring to form a tricyclic ring. Alternatively, Applicants respectfully request that Group IV, include the compounds of Groups II and III , wherein A is a 3-8 membered monocyclic saturated ring containing one to two heteroatoms, to which an aryl or heteroaryl ring is fused.

Applicants submit that the compounds of Requested Group IV represent alternatives under Rule 13.2(i), have the common property of being cannabinoid -1 receptor antagonists/inverse agonists that are useful to treat or prevent disorders, diseases or conditions responsive to the antagonism/inverse agonism of the cannabinoid -1 receptor, such as obesity, and diabetes. Applicants further submit that the common core structure of Requested Group IV, in which A is as defined above, constitutes a structurally distinctive portion of the molecule. Applicants submit that the "special technical relationship" that links the various putative inventions into a "single inventive concept" is the ability of the compounds of Requested Group IV to antagonize or inversely agonize the cannabinoid -1 receptor in a human or an animal.

Applicants submit that the methods of Group VIII are related to the compounds of Requested Group IV as product and process of use. Applicants further submit that a common technical feature is not lacking between Requested Group IV and Group VIII, since the primary active ingredient employed in the method claims in Group VIII is a compound with the core structural formula of Requested Group IV. Applicants therefore request that the method claims in Group VIII as they relate to the compounds of Requested Group IV be included in Requested Group IV. Applicants further request that Claim 23 as it relates to compositions of the compounds of Requested Group IV be included in Requested Group IV.

Applicants are required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims will be restricted if no generic claim is finally held to be allowable. Applicants hereby elect the compound of Examples 64 and 65 on page 161 of the specification as the elected species:



The following claims read on the elected species: 1-23.

Applicants make the above election with the understanding that, if the elected species is found to be allowable, the Examiner will examine the genus claims readable thereon and a reasonable number of disclosed species in addition to the elected species.

In light of the above reasons, Applicants respectfully request that the requirement for restriction between Groups I, II, III, IV, V, VI and VIII be withdrawn. In the event that the restriction requirement is made final, Applicants elect Group IV, as indicated, holding Groups I, II, III, V, VI and VIII in abeyance for further prosecution in a divisional application.

Applicants believe that all of the objections have been overcome and therefore earnestly solicit an early Notice of Allowance.

Respectfully submitted,

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